

REMARKS

Pending in this Application are Claims 1, 3, 5, 7, 13 – 15, 17, and 23 – 25.

Applicants have Claims 1, 3, 13, 14, and 23 in order to clarify that the growth factor component of the composition is a protein. Support for this amendment can be found at many places in the Specification, such as the paragraph beginning at Page 16, line 28.

I. Rejections Under 35 U.S.C. §103(a)

Claims 1, 3, 5, 7, 13 – 15, 17, and 23 – 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over European Patent No. 307847 (“EP 307847”), U.S. Patent No. 4,996,050 (“U.S. ‘050”), or International Patent Application No. WO 82/03772 (“WO 82/03772”), in view of European Patent No. 619370 (“EP 619370”), U.S. patent No. 5,589,451 (“U.S. ‘451”), U.S. Patent No. 5,814,605 (U.S. ‘605”), International Patent Application No. WO 97/13857 (“WO 97/13857”), or International Patent Application No. WO 98/16243 (“WO 98/16243”). The Examiner has asserted that the claims are unpatentable because the combination of a growth factor protein and a protease enzyme is obvious. Specifically, the Examiner states that “[i]f the ingredients are known individually in the art to be used for the same purpose, then to combine them for the same purpose is also obvious.” *See* Advisory Action dated August 12, 2004.

A protease enzyme, or protease, is defined as:

“Any of numerous enzymes that **hydrolyze proteins** and are classified according to the most prominent functional group (as serine or cysteine) at the active site -- called also *proteinase*.” *See* Merriam-Webster Dictionary 2004.

Thus, a **protease enzyme hydrolyzes, or destroys, proteins.**

Applicants assert that **the combination of a first element with a second element, when the second element is commonly known to digest and destroy the first element, is not an obvious combination.** Despite the fact that the two elements individually are used for the same

purpose, no one of skill in the art would expect that the combination of two incompatible elements would produce a useful result. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the **prior art also suggests the desirability of the combination**. See *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Nowhere in the prior art is there a suggestion of the desirability of combining a protein with an enzyme that destroys proteins to produce a useful composition. The rhetorical question is “Why would one want to combine a protein-degrading enzyme with a protein that can be degraded by the protein-degrading enzyme, unless the purpose is to get a degraded protein?”

Furthermore, there is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time of the invention. See *Smiths Industries Medical Systems Inc. v. Vital Signs Inc.*, 183 F.3d 1347, 51 U.S.P.Q.2d 1415, 1420 (Fed. Cir. 1999). **Even if growth factor proteins and protease enzymes were known in the art, common sense indicated that combining the two would be unproductive.** A person of skill in the art would expect that mixing the two components would produce a mixture of an inactive, degraded protein and an active protease enzyme. Such a mixture would be no more useful than a protease enzyme alone. However, the current claims pertain to a mixture producing unexpected results, or a synergistic utility that is greater than the use of a protease enzyme or a protein alone. See Specification at Page 19, lines 13 – 27. Where all elements of an invention were known in the prior art, but not utilized together, if the combination produces unexpected results different from the prior art, the invention may be patentable, particularly where the prior art indicates that the procedure utilized by the patent will be unproductive. See *Milgo Electronics Corp. v. United Telecommunications, Inc.*, 189 U.S.P.Q. 160, 168 (Kan. 1976); see also *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303, 312 (Fed. Cir. 1983); *In re Hedges*, 783 F.2d 1038, 228 U.S.P.Q. 685, 687 (Fed. Cir. 1986) (noting that proceeding contrary to the accepted wisdom of the prior art is strong evidence of nonobviousness).

II. **Conclusion**

For the reasons stated above, Applicants respectfully submit that Claims 1, 3, 5, 7, 13 – 15, 17, and 23 – 25 are patentable.

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,



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September 1, 2004

Date